

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M	A2	(11) International Publication Number: WO 95/04556 (43) International Publication Date: 16 February 1995 (16.02.95)
<p>(21) International Application Number: PCT/US94/08456</p> <p>(22) International Filing Date: 28 July 1994 (28.07.94)</p> <p>(30) Priority Data: 08/098,205 28 July 1993 (28.07.93) US</p> <p>(60) Parent Application or Grant (63) Related by Continuation US 08/098,205 (CON) Filed on 28 July 1993 (28.07.93)</p> <p>(71) Applicant (for all designated States except US): ACTIVE CONTROL EXPERTS, INC. [US/US]; 215 First Street, Cambridge, MA 02142 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): LAZARUS, Kenneth, B. [US/US]; 197 Beacon Street #2F, Boston, MA 02116 (US). CRAWLEY, Edward, F. [US/US]; 49B Dana Street, Cambridge, MA 02138 (US). FISH, Richard, David [US/US]; 6349 Vanderbilt Avenue, Houston, TX 77005 (US).</p> <p>(74) Agents: FALKOFF, Michael, I et al.; Lahive & Cockfield, 60 State Street, Boston, MA 02109 (US).</p>		<p>(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD).</p> <p>Published <i>Without international search report and to be republished upon receipt of that report.</i></p>
<p>(54) Title: REMOTELY STEERED CATHETERIZATION DEVICE</p> <p>(57) Abstract</p> <p>A remotely steerable guidewire, catheter or insertable active implement is disclosed. A steerable guidewire or a catheter for coronary and peripheral catheterizations is illustrated, using electrostrictive or piezoelectric material for controlling its motions inside the body via control inputs applied from outside the body. A steerable portion of the device, which may be either an active flexible tip or an active region along the length of the implement, controls the tip position or modifies stiffness along a region of the tip. In one embodiment, manipulation of electrical control inputs permits deflection of the steerable region through a range of motion about the axis of the implement in a single plane. In further embodiments, the tip may deflect in multiple planes about its longitudinal axis, or the device may be selectively stiffened to assume an arc shape or to firmly lodge the tip in position in a vessel.</p>		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

REMOTELY STEERED CATHETERIZATION DEVICE

Background of the Invention

5 The present invention relates to steering devices such as may be used with catheters, cannulae, guidewires and the like. More particularly, the present invention relates to catheters and guidewires that are steerable through body lumena or cavities, and are positioned within or aimed at obstructions, organs, or tissue within the body from a position external to the body.

10 Medical catheters generally comprise long tube-like members which may be inserted into the body, either percutaneously or via a body orifice, for any of a wide variety of diagnostic and interventional purposes. Such medical applications frequently require use of a catheter having the ability to negotiate twists and turns; this is particularly the case with
15 regard to certain cardiovascular applications.

 For such applications, the object is to reach and deliver some treatment or instrument to a remote lesion. Often, it is required that the instrument cross the lesion, which may consist of hard and inflexible tissue with a very rough surface, or even protruding flaps.

20 One such application, Percutaneous Transluminal Coronary Angioplasty (balloon angioplasty), requires manipulation of a catheter from a position outside the patient's body through extended portions of the patient's arterial system to the stenotic site for the purposes of alleviating the lesion by inflating a balloon. This particular procedure, performed with
25 increasing frequency over the past years, is done in preference to open heart bypass surgery, when possible.

 In a typical angioplasty procedure, a guidewire is first inserted transluminally into the brachial or the femoral artery, and advanced to a position within the stenotic region. A
30 balloon catheter is then placed over the guidewire and pushed to the desired location. In order to navigate the arterial branches and advance the guidewire, the cardiologist usually pre-bends the distal tip of the guidewire before insertion and then rotates (or torques) the wire once it has reached a branch artery to enable the tip of the guidewire to enter the branch. If the angle of the bend needs to be adjusted, the guidewire is removed, re-bent and reinserted,
35 sometimes several times during one angioplasty procedure. Particular difficulty is encountered with pre-bending in cases when an artery branches at one angle, and then sub-branches at a different angle. With repeated removal and reinsertion of the guidewire, the procedure is attended by the risk of significant trauma to the arterial lining, and in many cases, the obstruction cannot be reached at all with the guidewire and catheter.

Coronary arteries are tortuous and have many sub-branches. Often the obstruction is either located where the diameter of the artery is small or, by its very presence, the obstruction leaves only a very small opening through which a guidewire and/or catheter can be passed. Consequently the cardiologist often finds it very difficult to maneuver the guidewire or catheter, which is typically several feet long, from the proximal end.

In another application, Transluminal Laser Catheter Angioplasty (laser angioplasty), the delivery of laser energy from an external source to an intraluminal site to remove plaque or thrombus obstructions in vessels is accomplished by providing a waveguide such as a fiber optic bundle within a catheter. The nature of laser angioplasty requires even greater precision in control of the catheter, once it has reached a treatment site, to position and aim the laser light at the specific plaques or thrombi to be removed.

These applications could all benefit from an increased degree of steerability of the tip of the guidewire or catheter from a remote site located external to the body. A variety of constructions have been proposed in the past to provide catheters which are steerable from the proximal end to enable the catheter to be aimed or advanced through non-linear cavities without removal for adjustments. Such constructions include those shown in U.S. Patent 4,723,936 of Buchbinder; U.S. Patent 4,921,482 of Hammerslag; U.S. Patent 3,470,876 of Barchilon; U.S. Patent 4,601,705 of McCoy, and others. These constructions involve shape memory alloy elements which may be heated to change their orientation, or devices employing wires or pulleys to steer the tip of a device from a handle located outside the body. However, each of these constructions has limitations.

Shape memory alloy devices have slow response due to reliance on heat transfer as the operative control mechanism. Also, shape memory devices in their superelastic state have a great deal of hysteresis, making them difficult to use for controlling position precisely. Devices making use of wires and or pulleys for differential operation have problems achieving precise control over long distances, because long small diameter wires, requiring only minimal changes in length to actuate, do not afford very precise control. In addition, the cable tension required for such devices to work effectively dictates that the stiffness of the tip, which is critical to device effectiveness, is altered by the actuating mechanism. Also, the overall size of the device trades off against the ability to tension the cable, where the strain in the tensioned cable increases as device size decreases. It would therefore be desirable to achieve a remotely steerable catheterization device that does not incur penalties of stiffness, precision or size.

Summary of the Invention

It is therefore an object of the invention to achieve a remotely steerable catheterization device that does not sacrifice desirable traits.

5

It is another object of the invention to achieve such a device that is scaleable to steer instruments of varying sizes.

10 It is another object of the invention to achieve a remotely steerable catheterization device that has a controllable stiffness over a portion of its length.

In accordance with one aspect of the present invention, there is provided an improved instrument, which may be either a steerable guidewire or a catheter implement of the type useful for percutaneous transluminal insertion into the coronary vascular system. Controlled negotiation of branches and turns to guide an angioplasty catheter or guidewire to an arterial stenosis or lesion or other treatment site is achieved without the need for prebending by providing an active steering tip. Electronic signals control deflection of the distal tip of the instrument in one or more planes through a wide and continuous range of angles. In accordance with another aspect, movement or positioning of an implement is enhanced by controllably stiffening a segment or portion of the implement.

20 In one embodiment of the present invention, an actively steered guidewire is provided having an elongate flexible shaft with a central lumen carrying one or more electrically insulated wires to a tip formed at the distal end. The tip includes one or more layers of electrostrictive material, such as a piezoelectric ceramic material, bonded to sides of a thin metal shim, the piezoelectric ceramic layers preferably being poled and the electric signals from the wires attached such that a signal of one polarity causes one piezoelectric layer to extend, and the other piezoelectric layer to contract making the tip bend. The tip may include one or more pairs of oppositely straining piezoelectrics to produce tip flexing in one plane, in which case a full three-dimensional range of motion is achieved by torquing the shaft, and moving it forward. Or, in a further embodiment, the tip may include an additional pair, or pairs, of oppositely straining piezoelectrics to produce tip bending in a second, orthogonal plane. A full 360 degree range of radial motion is then achieved by the combined action of the two pairs, all commanded remotely by signals extending from the proximal end of the device.

35 In another embodiment, tip deflection is achieved by a lever-like tip with a piezoelectric element positioned eccentrically at the root of the tip to tilt or steer the lever.

In yet a third embodiment, a plurality of strain actuable elements are distributed along the length of the tip, and are selectively actuated to either induce a particular steering motion of the tip, to change the curvature of a portion of the tip, or to alter the stiffness of a portion in order to either advance, or anchor in place the position of the device.

5

The steerable device of the present invention thus negotiates tortuous and branched arterial systems, without the need for withdrawal and multiple insertions to deflect the tip.

10 Brief Description of the Drawings

These and other features of the present invention will be understood from the following drawings of illustrative embodiments, taken together with the detailed description, wherein

15

FIGURE 1 shows a perspective view, partly in schema, of a steerable catheterization device according to the present invention;

FIGURE 2 shows a detailed axial cross section of the tip assembly of a device such as
20 that of FIGURE 1;

FIGURES 3A-3C show three different architectures of a guidewire or catheter tip;

FIGURES 4A and 4B show two implementations of the tip architecture of FIGURE
25 3B;

FIGURES 5A, 5B and 5C show three embodiments of the implementation of
FIGURE 4A;

FIGURE 6 shows details of an active tip fabricated with coil spring and lubricous
30 coating;

FIGURE 7 shows a shaped guide catheter; and

FIGURE 8 shows a steering tip deflectable 360° about its longitudinal axis.
35

Detailed Description

FIGURE 1 shows a steerable catheterization device 10 in accordance with the present invention, which includes a handle 12, an elongated body 14, and an active tip assembly 16 that is controlled by the handle. Device 10 may be, for example, a guidewire such as is commonly inserted preparatory to placing a catheter into a position near to a patient's heart, or may be a catheter itself, such as is commonly used, for example to insert a balloon to that region for angioplasty. The tip assembly is bent away from the nominal axis "A" of the body, by virtue of one or more active elements. While not specifically shown, the handle 12 includes a mechanism of conventional type, for example a spring-loaded collet, that may be moved axially to grip the wire or body 14 and advance it inch by inch through the vascular system of a patient. The handle is preferably also adapted to rotate the wire as it advances, in order to steer the point of the off-axis tip assembly into branches or around curves as the body 14 is advanced along a vessel pathway. A control button 18 is ergonomically positioned on the handle 12 to control the provision of electrical actuation signals which are conducted through the body 14 to actuate the tip 16. This in turn controls the magnitude of off-axis deviation of the tip, or in some embodiments, the angle of tip direction in two planes or other tip characteristic.

As will be readily appreciated by those skilled in the art, the body 14 may be a guidewire, having a diameter of about .010 to .040 inches, a guide catheter having a diameter of about .060-.135 inches, or other form of catheter or catheter-based device. The general form also mirrors that of certain other insertable instruments, e.g., devices such as endoscopes and laparoscopy implements. Because of its small dimensions, a guidewire embodiment of the present invention offers the greatest challenges to implementation, and accordingly will be described below to best illustrate details of construction. The overall architecture of this tip is shown in FIGURE 3A, and includes an electrostrictive element acting against an inextensible element, such as a metal shim. The FIGURE illustrates a piezoelectric bimorph mounted as a steerable wiggler at the end.

FIGURE 2 shows a detailed cross-sectional view of the distal tip region 115 of one embodiment of a guidewire 114 in accordance with the present invention. Guidewire 114 includes a hollow wire body 117 approximately 36-48 inches long, and a steerable tip 119, which is approximately 5-10 inches long. By way of scale, body 117 is preferably formed of a thin metal tube, having an outer diameter illustratively .014 inches in diameter, with a wall thickness of .004-.005 inches, leaving a four to six mil lumen. The tubular wall has a high degree of torsional and compressional stiffness to resist twisting and buckling, while allowing the body to bend freely as it is steered and pushed along the vascular system. A tapered nose piece 121 is attached to the end of the tube 117, and extends the internal lumen while tapering

to a substantially smaller cross-section. Nose piece 121 may be formed of polycarbonate, stainless steel or the like. At the end of nose piece 121 an electrically actuated bending element 123 extends an additional one or two inches. Element 123 is actuated by one or more electrical conductors 125a, 125b which extend back through the body 117 to the control circuitry of the handle 12. The conductors are shown extending from the proximal end to the handle (FIGURE 1), but in alternate embodiments, they may reside entirely within body 117, and connect to surface access pads which are distributed along the body at its proximal end. In this case, the handle contacts the pads to apply control signals to element 123.

Surrounding the nose piece and bending element is a biocompatible and flexible spiral winding 127 which may, for example, be formed of one to three mil diameter platinum wire. An electrically insulating potting agent 128, such as a silicone elastomer, fills the space 130 between the bending element 123 and the biocompatible winding 127. The three structures together -- winding 127, potting medium 128 and the actuating element 123 -- have a high degree of flexibility comparable to that of a conventional (non-steered) guidewire. That is, the tip is floppy allowing the point to enter into branches and flex as it bumps its way around curves, while the elongated wire body 117 follows along. A thin outer shell or lubricous film such as polyurethane film (not shown), may encase the assembly to reduce friction of the device in the artery. By way of scale, the distances "a" and "b" may be, for example, two to seven inches, and one to two inches, respectively.

In accordance with a principal aspect of the invention, element 123 is electrically actuated by a driving voltage from outside to bend the tip off the longitudinal axis by an amount which, in the illustrated embodiment, is controlled up to a deviation calculated to exceed thirty degrees. A deflected position is indicated by "d" in phantom in the FIGURE. Greater deflections may be achieved by lengthening the element 123. Furthermore, the deflected tip may be rotated 360° about the longitudinal axis by torquing the insertion handle 12.

In the presently preferred embodiment of the invention, the electrostrictive actuators constituting the adjustable element are fabricated out of piezoceramic plates, which are thinned to a dimension such that a completed multi-layer assembly made with the plates has a passive or non-actuated state bending stiffness comparable to the stiffness of a conventional wire steering tip, while remaining strong enough to deflect the tip when actuated. Furthermore, the plates are made thin enough such that actuation fields above many hundreds of volts per millimeter can be applied using biologically safe signal levels, e.g., using an actuating signal below about thirty volts, with a current below 200 μ a.

In the illustrated construction, the electrically actuated element is formed with first and second strips of piezoelectric material 132, 134 bonded to opposite sides of a thin and inextensible metal strip 135, and poled in opposite senses. The metal strip 135 serves as a common electrode for actuation of the elements, while two wires 125a, 125b are connected to
5 respective opposing plates.

To achieve a suitable flexibility, for a guidewire having a diameter under about .35 millimeters, the plates 132, 134 may, for example, be formed of lead zirconium titanate (PZT), worked to a thickness of about .025 millimeters, and cut in strips .15 millimeters
10 wide; the metal strip 135 may be about .025 millimeters thick, and also about .15 millimeters wide. The plates 132, 134 are two to four centimeters long, and preferably the metal shim extends another centimeter or more to the tip of the catheter or wire assembly. A solder dot 136 seals the end, enclosing the metal shim 135 and plates 132, 134 within the wire wrap 127, which as shown is filled with a potting medium 128. With this construction the fragile
15 tip element is securely protected against fragments of PZT leaking out into the blood stream in the event of a fracture, while the entire tip assembly remains as supple and flexible as a prior art wire steering tip.

Electrical actuation of the device of FIGURE 2 is performed via leads 125a, 125b
20 which are connected to outer electrode surfaces of the plates 132, 134, and preferably also by the common electrode formed by the thin metal strip 135. The common electrode may be conductively connected to plated or metalized lines on the surface of the nose piece 121 (if a non-conductive material is used to form the nose piece) which, in turn, contact the conductive metal wire body 117, or may be connected to a separate insulated lead extending through the
25 nosepiece.

As noted above, the dimensional limitations of a guidewire render the implementation of an active piezoelectric steering tip challenging. The thin plates of lead zirconium titanate are formed by taking plates of small grain, low void lead zirconium titanate of several times
30 greater thickness (e.g., .125, .175, or .25 millimeter plates, as available commercially from suppliers such as Edo, Morgan Matroc, or American Piezoceramics), bonding a plate with a high strength conductive adhesive to each side of a one mil metal sheet, to form a very high shear strength thin bonding layer, and then lapping the outer faces on an optical grinding or lapping jig to achieve a .025 millimeter thickness of each piezoceramic plate. The outer faces
35 of each piezoceramic plate are then metallized, preferably with gold or other biocompatible metal, to form electrode surfaces, and are then laser cut into strips .15 millimeters wide. After fabrication, the piezoceramic material is poled, by application of a high electric field between the conductive electrode faces. This produces a completed piezo bender unit for incorporation into the steering tip.

In addition to achieving a high degree of flexibility in the plates 132, 134, the thin dimensions result in an actuator that operates with low actuation voltages, so that full displacements are readily achieved with signals below thirty volts and one hundred fifty
5 microamperes or less. This allows the device to be actuated by a current-limited electrical control signal, that is safe even in the event of leakage or a short circuit of wires 125a, 125b and body 117. In addition, sufficient actuation signals of this level may be provided by batteries located within the handle 12, so that the instrument is free of external power connections.

10

In other embodiments, different electrostrictive or piezoelectric elements may be used.

FIGURE 3C illustrates an architecture wherein a steering tip 200 is formed by a lever
15 arm 201 flexibly but inextensibly attached by a central wire 202, which acts as a hinge or pivot holding the arm 201 to a body 203 which corresponds to the guidewire 117 of the preceding embodiment, or to a catheter. A piezoelectric post or stack 205 extends off-center and is operated in extension to rock the lever 201 to a desired angle. As in the preceding embodiments, the joint bearing the piezo actuating element is preferably encased and
20 encapsulated, e.g., by a sheath or wire wrap, and potting material.

FIGURE 3B shows a third tip architecture 300. In this embodiment the bending tip
301 may be formed with a single metal shim extending the full length of the bending region (as in FIGURES 3A or 2), but a plurality of piezoceramic plates or sheet elements are
25 positioned at discrete separated positions along the metal shim to induce different degrees of bending. As in the device of FIGURE 2, the plates are arranged on opposite sides to form piezo benders which are localized along the tip length. When stiffness and dimensional constraints permit sufficient electrical leads, this embodiment may be actuated to undergo more complex bends, such as S-shaped bends, or may be actuated to bend at one position
30 while stiffening the tip at a different position.

In accordance with a principal method of use of the present invention, the guidewire
or catheter device is advanced within the vascular system of a patient, e.g., via the femoral artery, and is simultaneously visualized using a contrast medium under a fluoroscope. As the
35 tip nears an arterial branch point or narrowed passage, control signals are applied from the handle to steer the tip, changing its direction as required to an appropriate angle or position, and the device is then rotated (if necessary, as it is for a one-dimensional deflector tip) and advanced further.

In accordance with another method of use in accordance with the invention, the tip may be actuated to assume an arc-shape that anchors it in position in a particular position, such as in the aortic arch. For effecting this latter method, the active strain elements of the tip assembly are preferably mounted over an extended length, perhaps four to six inches, ahead of the tip area. In this case, the elements may be actuated to form a smooth arc of a radius that matches the arch curvature, so that the catheter resides in position without irritating the vessel walls. Alternatively, the elements may be actuated so that the catheter assumes a larger or smaller curvature, or has several polygonal bends, thus making it contact the wall in several places to anchor it against sliding or creeping out of position.

10

By way of particular example, the device may be a tube 600 as shown in FIGURE 7 which is preformed to assume an arc-shape to position it in the aortic arch 70. Tube 600 has a pair of sharp bends or elbows, 602, 604 which are spaced to fit the arch, but which have relatively low bending stiffness, so that the tube readily straightens and passes through the patient's vessels during the insertion procedure. However, each elbow has respective piezoelectric strain elements 603, 605 mounted about the elbow. These are actuated, once the tube has been positioned, to rigidify the bends and firmly lodge the tube in the desired position to support passage of coaxial catheters and wires within the lumen.

15

In accordance with yet a third method in accordance with the present invention, actuators may be energized to stiffen the tip or a portion of the tip assembly along its length to rigidify it for entering a branch point or passing an obstruction. Advantageously, by employing electrical signals to stiffen a region of the catheter or wire, the stiffness of the non-actuated positions of the wire or catheter body 117 remains flexible and unaffected.

20

FIGURES 4A and 4B illustrate two methods of tip actuator placement, shown here for a guide catheter. In FIGURE 4A a tip assembly 400 has a plurality of identically-sized strain actuators 405 placed on opposed sides of the tip at a number of equally-spaced intervals along its length, along a region where bending is desired, an inch or two from the end. In FIGURE 4B, a tip assembly 410 has both larger strain elements 415 and smaller elements 416, which may be positioned to optimize one or more properties, such as to maximize deflection, avoid fracture of the elements, or speed up the response time of the actuator. Preferably, smaller elements are located at joint or flexure areas.

25

FIGURES 5A-5C illustrate variations in actuator placement along the tip, either at the extreme end (FIGURE 5A), an inch or two back (FIGURE 5B) or extending over a major segment of both regions of the end (FIGURE 5C). In the latter case, elements at one position may be wired oppositely to those at another position to form a zig-zag rather than a single

30

35

bend. Such shape, in conjunction with conventional torquing (rotation) of the wire or catheter body may offer enhanced vessel branch navigation abilities.

5 Preferably the overall tip construction is a multi-layered construction as illustrated in FIGURE 6, with an insulating but flexible sheath and a protective coil exterior, as described in respect of FIGURE 2, above.

FIGURE 8A, 8B and 8C illustrate, greatly enlarged, one embodiment of a tip construction 500 for bending along two degrees of freedom about the longitudinal axis "L" of a steered insertable device. First and second steel shims 510, 511 are mounted to cross each other as a pair of crossing vanes with oppositely-actuated strain elements 550a, 550b, and 551a, 551b positioned on the respective shims to deflect them in first and second planes, respectively. Geometric constraints due to the small geometry are largely avoided by mounting the strain actuators of each vane on opposite faces of the vane, and opposite sides of the vane's crossing axis 520. Furthermore, the actuators of the first vane are mounted at a different position along the axis L, than are the actuators of the second vane. Thus, as illustrated in perspective view FIGURE 8A, the first set 550a, 550b bends the tip in the plane of the drawing, when actuated, while the second set causes out-of-plane deflections.

20 It will be understood that the constructions described above for guidewires, may be readily scaled to form an active steerable tip for a guide catheter, for a related instrument incorporating catheter or wire features, such as a balloon pump, or for an endoscope or specialized treatment device. In such cases, when devices are generally of greater diameter but the inner lumen must remain open, it may be desirable to use other strain actuated materials, such as polyvinylidene difluoride (PVDF), which may be bonded to the outside of the catheter, but below a protective layer. While generally capable of applying less force, PVDF actuators on larger tubes or catheters may benefit from the larger moment arm from the neutral axis. Further increases in mechanical advantage are obtained by mounting on the outer skin of the tube or catheter. Alternatively, one or more layers of a piezoelectric polymer material may form the tip body itself. In general, however, constructions using piezoceramics as described above, are preferred for their greater force characteristics and desirable low level signal requirements.

35 The invention being thus disclosed, further variations and modifications will occur to those skilled in the art, and all such variations and modifications are intended to be within the scope of the invention, as defined in the claims appended hereto.

Claims

1. A remotely steerable catheterization device, such device comprising
an elongated body having proximal and distal ends, and being axially
5 incompressible for advancing within a patient's body when pushed from the proximal end
a steering tip at the distal end
electrical conduction means extending in said body from the proximal
end to the steering tip, and
an electrostrictive strain element mounted to act against an inextensible
10 member at said steering tip for controllably deflecting the steering tip in response to control
signals applied thereto, said steering element means receiving control signals via said
electrical conductor means to steer the tip from said proximal end.
2. A remotely steerable catheterization device according to claim 1, wherein said
15 body is tubular.
3. A remotely steerable catheterization device according to claim 1, wherein said
body is a guidewire.
- 20 4. A remotely steerable catheterization device according to claim 1, wherein said
body is a guide catheter.
5. A remotely steerable catheterization device according to claim 1, wherein said
body is a catheter having a lumen for effecting a diagnostic or treatment regimen at said tip
25 via said lumen.
6. A remotely steerable catheterization device according to claim 1, wherein said
strain element is a piezoelectric bender.
- 30 7. A remotely steerable catheterization device according to claim 1, wherein said
steering tip includes a lever arm that is displaced by actuating a piezoelectric element.
8. A remotely steerable catheterization device according to claim 1, wherein said
strain element includes plural distinct strain actuators placed at axially-separated positions
35 along said steering tip.
9. A remotely steerable catheterization device according to claim 8, wherein said
plural distinct strain actuators include actuators of different sizes.

10. A remotely steerable catheterization device according to claim 8, wherein said strain element includes piezoelectric elements of a thickness to be fully actuated by a signal that is safe for cardiac applications.

5 11. A remotely steerable catheterization device according to claim 1, wherein said strain element includes piezoceramic material having a stiffness approximating a stiffness of a cardiac catheterization guidewire.

10 12. A remotely steerable catheterization device according to claim 1, wherein said strain element means includes a piezoelectric actuator extending over a substantial length of the tip for holding the tip in a stiff curve.

13. A remotely steerable catheterization device according to claim 1, further comprising a control handle with means for advancing the distal end by pushing said body.
15

14. A remotely steerable catheterization device according to claim 13, wherein said handle includes electrical means for applying electrical steering signals to said electrical conduction means.

20 15. An insertable catheterization device comprising
an elongated body having proximal and distal ends, for advancing
within a patient's body when pushed from the proximal end
a steering tip at the distal end
electrical conductors extending in said body from the proximal end,
25 and
a plurality of strain elements mounted in said device for receiving electrical
actuation signals via said electrical conductors to physically control said device from its
proximal end.

30 16. An insertable catheterization device according to claim 15, wherein said plurality of strain elements are distributed along the body for stiffening the body to lodge it securely in position within a vessel.

35 17. An insertable catheterization device according to claim 15, wherein said plurality of strain elements are distributed at said steering tip for actively bending the tip.

18. An insertable catheterization device according to claim 15, wherein said plurality of strain elements include at least one of a piezoceramic, a crystal, and a piezoelectric polymer material.

19. A device for insertion into the body of a patient, such device comprising
an elongated body
a tip
5 strain elements extending along at least one inextensible portion of the body or
of the tip
conductive means for delivering a signal to the strain elements, and
control means for selectively providing a signal to the conductive means to
physically control the portion covered by the strain elements.
- 10 20. A method of making a high compliance piezoelectric actuator, such method
comprising the steps of
bonding a prebaked piezoceramic sheet to one side of a sheet of shim material
lapping an outer surface of the piezoceramic sheet to thin it to a final thickness
15 below .1 millimeters, and
forming an electrode surface on the outer surface, thereby achieving an
electrically actuatable sheet, the final thickness being selected to achieve a desired degree of
mechanical compliance.
- 20 21. The method of claim 20, wherein the final thickness is further selected to
achieve actuation of the electrically actuatable sheet with a potential of under about thirty volts.
22. The method of claim 20, further comprising the step of laser cutting the
electrically actuatable sheet into pieces sized and shaped for fitting into a catheterization
25 device.
23. The method of claim 20, comprising the steps of lapping and forming an
electrode face on a second prebaked piezoceramic sheet bonded to an opposite side of said
shim material to achieve a piezoelectric bender having said desired degree of compliance.

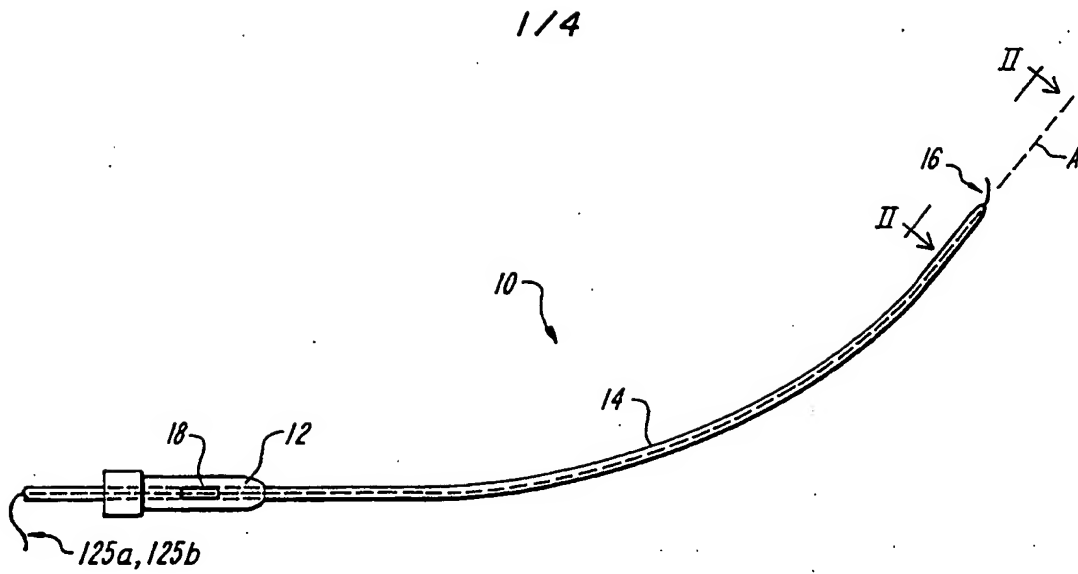


FIG. 1

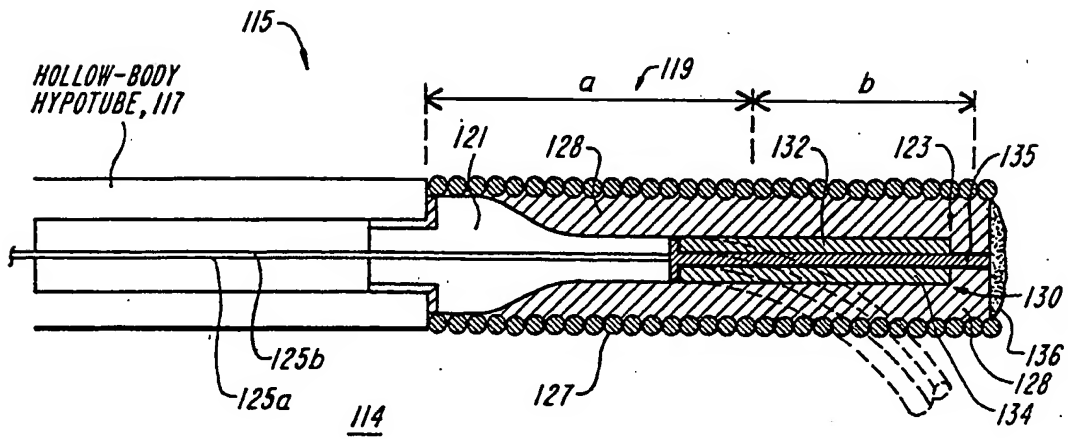


FIG. 2

2/4



FIG. 3A

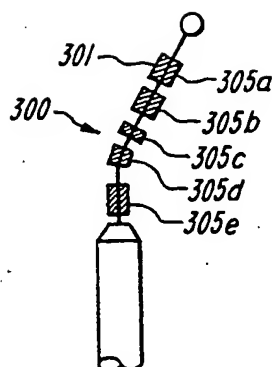


FIG. 3B

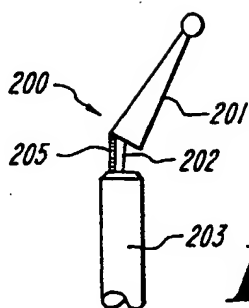


FIG. 3C



FIG. 5A

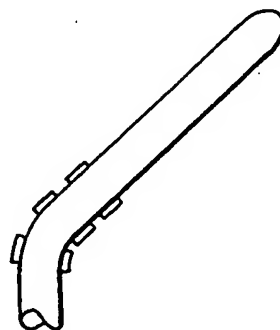


FIG. 5B

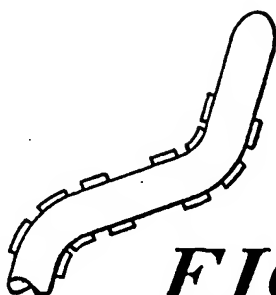


FIG. 5C

SUBSTITUTE SHEET (RULE 26)

BEST AVAILABLE COPY

3/4

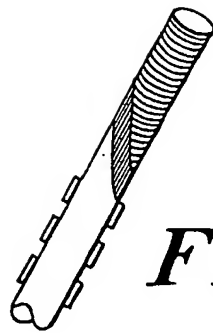


FIG. 6

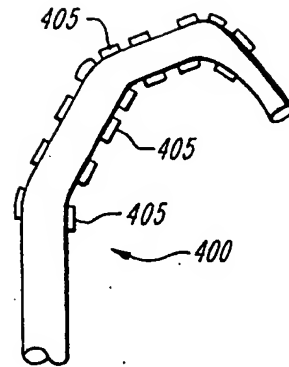


FIG. 4A

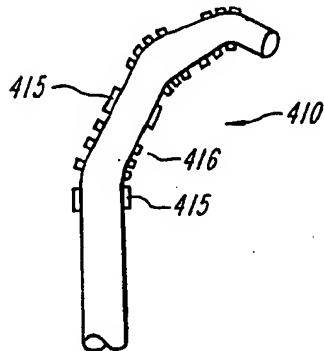


FIG. 4B

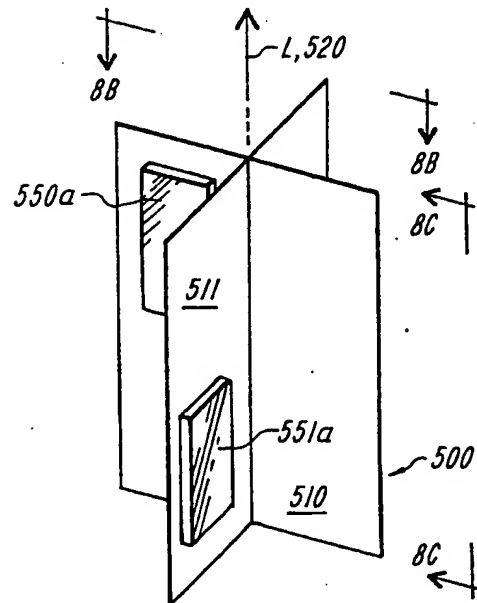


FIG. 8A

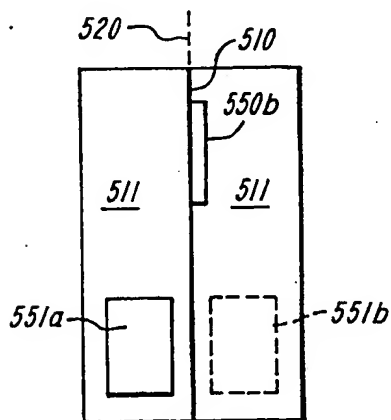


FIG. 8C

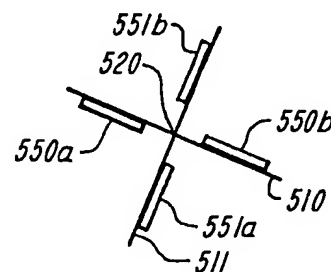
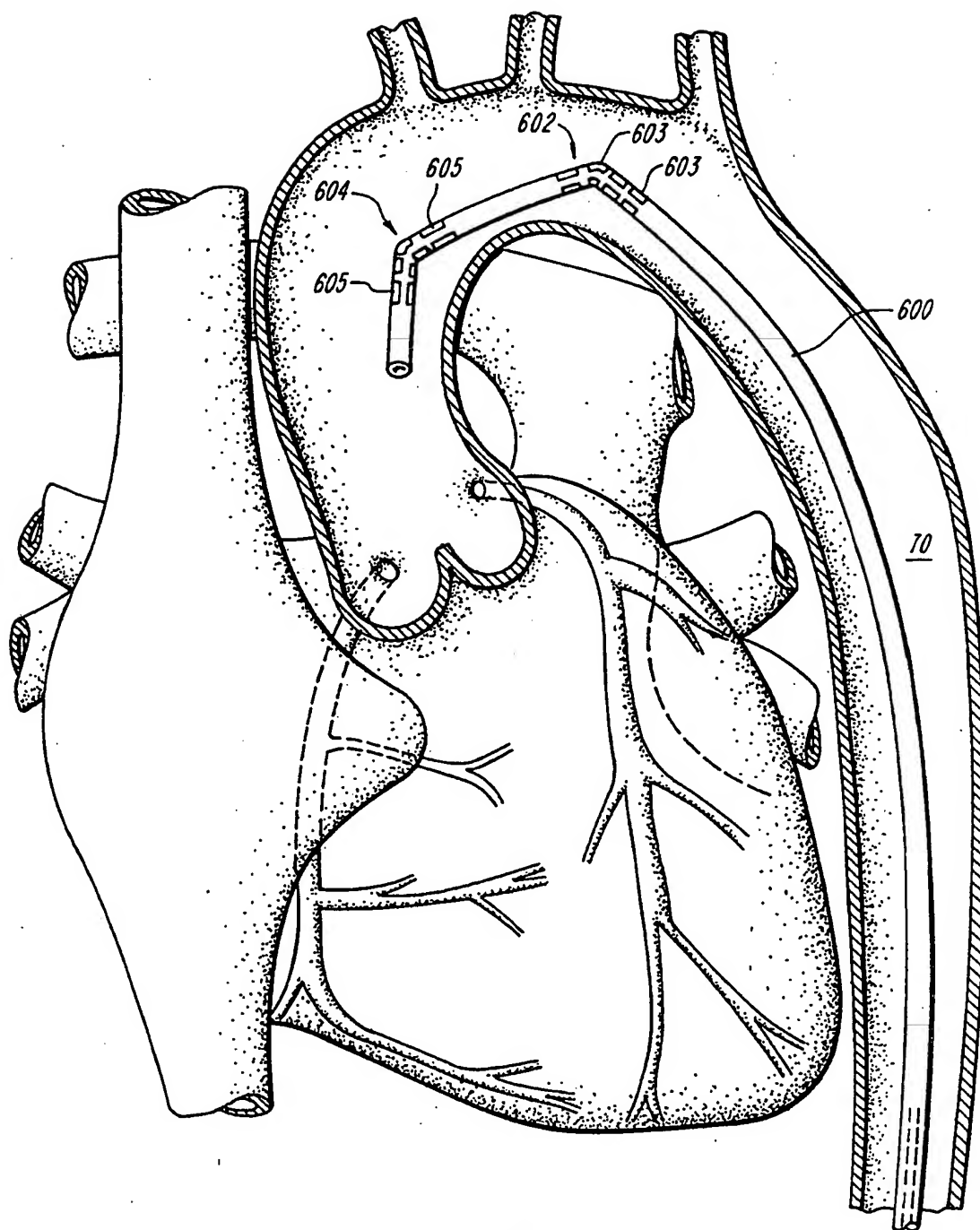


FIG. 8B

4/4

**FIG. 7**